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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification ⁶ : A61K 31/365	A3	(11) International Publication Number: WO 98/01100 (43) International Publication Date: 15 January 1998 (15.01.98)								
(21) International Application Number: PCT/US97/11792 (22) International Filing Date: 3 July 1997 (03.07.97) (30) Priority Data: <table border="0"><tr><td>60/021,420</td><td>9 July 1996 (09.07.96)</td><td>US</td></tr><tr><td>9617898.3</td><td>28 August 1996 (28.08.96)</td><td>GB</td></tr><tr><td>60/029,351</td><td>31 October 1996 (31.10.96)</td><td>US</td></tr></table> (71) Applicant (for all designated States except US): MERCK & CO., INC. [US/US]; 126 East Lincoln Avenue, Rahway, NJ 07065 (US). (72) Inventors; and (75) Inventors/Applicants (for US only): MITCHEL, Yale, B. [US/US]; 126 East Lincoln Avenue, Rahway, NJ 07065 (US). TOBERT, Jonathan, A. [US/US]; 126 East Lincoln Avenue, Rahway, NJ 07065 (US). (74) Common Representative: MERCK & CO., INC.; 126 East Lincoln Avenue, Rahway, NJ 07065 (US).	60/021,420	9 July 1996 (09.07.96)	US	9617898.3	28 August 1996 (28.08.96)	GB	60/029,351	31 October 1996 (31.10.96)	US	(81) Designated States: AL, AM, AU, AZ, BA, BB, BG, BR, BY, CA, CN, CU, CZ, EE, GE, HU, IL, IS, JP, KG, KR, KZ, LC, LK, LR, LT, LV, MD, MG, MK, MN, MX, NO, NZ, PL, RO, RU, SG, SI, SK, SL, TJ, TM, TR, TT, UA, US, UZ, VN, YU, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i> <i>Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i> (88) Date of publication of the international search report: 12 February 1998 (12.02.98)
60/021,420	9 July 1996 (09.07.96)	US								
9617898.3	28 August 1996 (28.08.96)	GB								
60/029,351	31 October 1996 (31.10.96)	US								
(54) Title: METHOD FOR TREATING HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (57) Abstract Homozygous familial hypercholesterolemia can be treated in patients suffering with this condition by administering a therapeutically effective amount of simvastatin. Dosages above 40 mg/day, and more particularly at or above 80 mg/day, were found to effectively reduce the LDL cholesterol levels in these patients.										

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DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US97/11792

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61K 31/365

US CL :514/460

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 514/460

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

CHEMICAL ABSTRACTS

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	Randomised trial of cholesterol lowering in 4444 patients with coronary heart disease: the Scandinavian Simvastatin Survival Study (4S). Lancet. November 1994, Vol. 19:344, pages 1383-9 (1994) (Abstract).	1-9
A	US, 5,393,893 A (KUBELA et al.) 28 February 1995, see entire document.	1-9
A	US, 4,997,849 A (PETUCH et al.) 05 March 1991, see entire document.	1-9

☐ Further documents are listed in the continuation of Box C.
 ☐ See patent family annex.

A	document defining the general state of the art which is not considered to be of particular relevance	*T*	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
E	earlier document published on or after the international filing date	*X*	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
L	documents which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reasons (as specified)	*Y*	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
O	document referring to an oral disclosure, use, exhibition or other means	*A*	document member of the same patent family
P	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

03 NOVEMBER 1997

Date of mailing of the international search report

15 DEC 1997

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

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185/39/61

DIALOG(R)File 345:Inpadoc/Fam.& Legal Stat
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13245748

Basic Patent (No,Kind,Date): GB 9617898 A0 19961009 <No. of Patents: 007>

Patent Family:

Patent No	Kind	Date	Applic No	Kind	Date	
AU 9736672	A1	19980202	AU 9736672	A	19970703	
AU 9742289	A1	19980202	AU 9742289	A	19970703	
AU 9743261	A1	19980202	AU 9743261	A	19970703	
GB 9617898	A0	19961009	GB 9617898	A	19960828	(BASIC)
WO 9801116	A1	19980115	WO 97US12426	A	19970703	
WO 9801100	A2	19980115	WO 97US11792	A	19970703	
WO 9801119	A2	19980115	WO 97US10867	A	19970703	

Priority Data (No,Kind,Date):

GB 9617898 A 19960828
US 21420 P 19960709
US 29351 P 19961031
WO 97US12426 W 19970703
WO 97US11792 W 19970703

WO 97US10867 W 19970703

PATENT FAMILY:

AUSTRALIA (AU)

Patent (No,Kind,Date): AU 9736672 A1 19980202
THERAPY FOR COMBINED HYPERLIPIDEMIA (English)
Patent Assignee: MERCK & CO INC
Author (Inventor): MITCHEL YALE B; MELINO MICHAEL R
Priority (No,Kind,Date): GB 9617898 A 19960828; US 21420 P
19960709; US 29351 P 19961031; WO 97US12426 W 19970703
Applic (No,Kind,Date): AU 9736672 A 19970703
IPC: * A61K-009/20
CA Abstract No: * 128(09)097715J; 128(09)097716K; 128(11)132435S
Derwent WPI Acc No: * C 98-110203; C 98-110207; C 98-145191
Language of Document: English
Patent (No,Kind,Date): AU 9742289 A1 19980202
METHOD FOR TREATING HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (English)
Patent Assignee: MERCK & CO INC
Author (Inventor): MITCHEL YALE B; TOBERT JONATHAN A
Priority (No,Kind,Date): GB 9617898 A 19960828; US 21420 P
19960709; US 29351 P 19961031; WO 97US11792 W 19970703
Applic (No,Kind,Date): AU 9742289 A 19970703
IPC: * A61K-031/00
CA Abstract No: * 128(09)097715J; 128(09)097716K; 128(11)132435S
Derwent WPI Acc No: * C 98-110203; C 98-110207; C 98-145191
Language of Document: English
Patent (No,Kind,Date): AU 9743261 A1 19980202
PHARMACEUTICAL COMPOSITIONS (English)
Patent Assignee: MERCK & CO INC
Author (Inventor): MITCHEL YALE B; TOBERT JONATHAN A
Priority (No,Kind,Date): GB 9617898 A 19960828; US 21420 P
19960709; US 29351 P 19961031; WO 97US10867 W 19970703
Applic (No,Kind,Date): AU 9743261 A 19970703
IPC: * A61K-031/00
CA Abstract No: * 128(09)097715J; 128(09)097716K; 128(11)132435S
Derwent WPI Acc No: * C 98-110203; C 98-110207; C 98-145191
Language of Document: English

GREAT BRITAIN (GB)

Patent (No,Kind,Date): GB 9617898 A0 19961009
METHOD FOR TREATING HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (English)
Patent Assignee: MERCK & CO INC
Priority (No,Kind,Date): GB 9617898 A 19960828
Applic (No,Kind,Date): GB 9617898 A 19960828
Language of Document: English

WORLD INTELLECTUAL PROPERTY ORGANIZATION, PCT (WO)

Patent (No,Kind,Date): WO 9801116 A1 19980115
THERAPY FOR COMBINED HYPERLIPIDEMIA (English)
Patent Assignee: MERCK & CO INC (US); MITCHEL YALE B (US); MELINO
MICHAEL R (US)
Author (Inventor): MITCHEL YALE B (US); MELINO MICHAEL R (US)
Priority (No,Kind,Date): GB 9617898 A 19960828; US 21420 P
19960709; US 29351 P 19961031
Applic (No,Kind,Date): WO 97US12426 A 19970703
Designated States: (National) AL; AM; AU; AZ; BB; BG; BR; BY; CA; CN;
CZ; EE; GE; HU; IL; IS; JP; KG; KR; KZ; LK; LR; LT; LV; MD; MG; MK;

MN; MX; NO; NZ; PL; RO; RU; SG; SI; SK; SL; TJ; TM; TR; TT; UA; US;
UZ; VN; YU; AM; AZ; BY; KG; KZ; MD; RU; TJ; TM (Regional) GH; KE;
LS; MW; SD; SZ; UG; ZW; AT; BE; CH; DE; DK; ES; FI; FR; GB; GR; IE;
IT; LU; MC; NL; PT; SE; BF; BJ; CF; CG; CI; CM; GA; GN; ML; MR; NE;
SN; TD; TG

Filing Details: WO 100000 With international search report

IPC: * A61K-009/20

CA Abstract No: * 128(09)097715J; 128(09)097716K; 128(11)132435S;
128(09)097716K

Derwent WPI Acc No: * C 98-110203; C 98-110207; C 98-145191; C
98-110207

Language of Document: English

Patent (No,Kind,Date): WO 9801100 A2 19980115

METHOD FOR TREATING HOMOZYGOUS FAMILIAL HYPERCHOLESTEROLEMIA (English)

Patent Assignee: MERCK & CO INC (US); MITCHEL YALE B (US); TOBERT
JONATHAN A (US)

Author (Inventor): MITCHEL YALE B (US); TOBERT JONATHAN A (US)

Priority (No,Kind,Date): GB 9617898 A 19960828; US 21420 P
19960709; US 29351 P 19961031

Applic (No,Kind,Date): WO 97US11792 A 19970703

Designated States: (National) AL; AM; AU; AZ; BA; BB; BG; BR; BY; CA;
CN; CU; CZ; EE; GE; HU; IL; IS; JP; KG; KR; KZ; LC; LK; LR; LT; LV;
MD; MG; MK; MN; MX; NO; NZ; PL; RO; RU; SG; SI; SK; SL; TJ; TM; TR;
TT; UA; US; UZ; VN; YU; AM; AZ; BY; KG; KZ; MD; RU; TJ; TM
(Regional) GH; KE; LS; MW; SD; SZ; UG; ZW; AT; BE; CH; DE; DK; ES; FI
; FR; GB; GR; IE; IT; LU; MC; NL; PT; SE; BF; BJ; CF; CG; CI; CM; GA;
GN; ML; MR; NE; SN; TD; TG

Filing Details: WO 130000 With international search report; Before
expiration of time limit for amending the claims and to be
republished in the event of the receipt of the amendments

IPC: * A61K

CA Abstract No: * 128(09)097715J; 128(09)097716K; 128(11)132435S;
128(09)097715J

Derwent WPI Acc No: * C 98-110203; C 98-110207; C 98-145191; C
98-110203

Language of Document: English

Patent (No,Kind,Date): WO 9801119 A2 19980115

PHARMACEUTICAL COMPOSITIONS (English)

Patent Assignee: MERCK & CO INC (US); MITCHEL YALE B (US); TOBERT
JONATHAN A (US)

Author (Inventor): MITCHEL YALE B (US); TOBERT JONATHAN A (US)

Priority (No,Kind,Date): GB 9617898 A 19960828; US 21420 P
19960709; US 29351 P 19961031

Applic (No,Kind,Date): WO 97US10867 A 19970703

Designated States: (National) AL; AM; AU; AZ; BB; BG; BR; BY; CA; CN;
CZ; EE; GE; HU; IL; IS; JP; KG; KR; KZ; LK; LR; LT; LV; MD; MG; MK;
MN; MX; NO; NZ; PL; RO; RU; SG; SI; SK; SL; TJ; TM; TR; TT; UA; US;
UZ; VN; YU; AM; AZ; BY; KG; KZ; MD; RU; TJ; TM (Regional) GH; KE;
LS; MW; SD; SZ; UG; ZW; AT; BE; CH; DE; DK; ES; FI; FR; GB; GR; IE;
IT; LU; MC; NL; PT; SE; BF; BJ; CF; CG; CI; CM; GA; GN; ML; MR; NE;
SN; TD; TG

Filing Details: WO 300000 Without international search report and to
be republished upon receipt of that report

IPC: * A61K-031/00

CA Abstract No: * 128(09)097715J; 128(09)097716K; 128(11)132435S;
128(11)132435S

Derwent WPI Acc No: * C 98-110203; C 98-110207; C 98-145191; C

98-145191
Language of Document: English

WORLD INTELLECTUAL PROPERTY ORGANIZATION, PCT (WO)

Legal Status (No, Type, Date, Code, Text):

WO 9801100	P	19960709	WO AA	PRIORITY CLAIMED
		US 21420	P	19960709
WO 9801100	P	19960828	WO AA	PRIORITY (PATENT)
		GB 9617898	A	19960828
WO 9801100	P	19961031	WO AA	PRIORITY CLAIMED
		US 29351	P	19961031
WO 9801100	P	19970703	WO AE	APPLICATION DATA (APPL. DATA)
		WO 97US11792	A	19970703
WO 9801100	P	19980115	WO AK	DESIGNATED STATES CITED IN A PUBLISHED APPLICATION WITHOUT SEARCH REPORT (DESIGNATED STATES CITED IN A PUBLISHED APPL. WITHOUT SEARCH REPORT)
		AL AM AU AZ BA BB BG BR BY CA CN CU CZ EE GE HU IL IS JP KG KR KZ LC LK LR LT LV MD MG MK MN MX NO NZ PL RO RU SG SI SK SL TJ TM TR TT UA US UZ VN YU AM AZ BY KG KZ MD RU TJ TM		
WO 9801100	P	19980115	WO AL	DESIGNATED COUNTRIES FOR REGIONAL PATENTS CITED IN A PUBLISHED APPLICATION WITHOUT SEARCH REPORT (DESIGNATED COUNTRIES FOR REGIONAL PATENTS CITED IN A PUBLISHED APPL. WITHOUT SEARCH REPORT)
		GH KE LS MW SD SZ UG ZW AT BE CH DE DK ES FI FR GB GR IE IT LU MC NL PT SE BF BJ CF CG CI CM GA GN ML MR NE SN TD TG		
WO 9801100	P	19980115	WO A2	PUBLICATION OF THE INTERNATIONAL APPLICATION WITHOUT THE INTERNATIONAL SEARCH REPORT (PUB. OF THE INTERNATIONAL APPL. WITHOUT THE INTERNATIONAL SEARCH REPORT)
WO 9801100	P	19980326	WO DFPE	REQUEST FOR PRELIMINARY EXAMINATION FILED PRIOR TO EXPIRATION OF 19TH MONTH FROM PRIORITY DATE
WO 9801100	P	19980520	WO 121	EP: PCT APP. ART. 158 (1) (EP: PCT ANM. ART. 158 (1))
WO 9801100	P	19990604	WO NENP	<u>NON-ENTRY INTO THE NATIONAL PHASE IN:</u>
		<u>JP</u>	1998505308	
WO 9801100	P	20000109	WO NENP	<u>NON-ENTRY INTO THE NATIONAL PHASE IN:</u>
		<u>CA</u>		
WO 9801100	P	20000209	WO 122	<u>EP: PCT APP. NOT ENT. EUROP. PHASE (EP: PCT ANM. NICHT IN EUROP. PHASE EING.)</u>
WO 9801116	P	19960709	WO AA	PRIORITY CLAIMED
		US 21420	P	19960709
WO 9801116	P	19960828	WO AA	PRIORITY (PATENT)
		GB 9617898	A	19960828
WO 9801116	P	19961031	WO AA	PRIORITY CLAIMED
		US 29351	P	19961031
WO 9801116	P	19970703	WO AE	APPLICATION DATA (APPL. DATA)

DATA)
WO 97US12426 A 19970703

WO 9801116 P 19980115 WO AK DESIGNATED STATES CITED IN A
PUBLISHED APPLICATION WITH SEARCH REPORT
(DESIGNATED STATES CITED IN A PUBLISHED APPL.
WITH SEARCH REPORT)
AL AM AU AZ BB BG BR BY CA CN CZ EE GE HU IL
IS JP KG KR KZ LK LR LT LV MD MG MK MN MX NO
NZ PL RO RU SG SI SK SL TJ TM TR TT UA US UZ
VN YU AM AZ BY KG KZ MD RU TJ TM

WO 9801116 P 19980115 WO AL DESIGNATED COUNTRIES FOR
REGIONAL PATENTS CITED IN A PUBLISHED
APPLICATION WITH SEARCH REPORT (DESIGNATED
COUNTRIES FOR REGIONAL PATENTS CITED IN A
PUBLISHED APPL. WITH SEARCH REPORT)
GH KE LS MW SD SZ UG ZW AT BE CH DE DK ES FI
FR GB GR IE IT LU MC NL PT SE BF BJ CF CG CI
CM GA GN ML MR NE SN TD TG

WO 9801116 P 19980115 WO A1 PUBLICATION OF THE
INTERNATIONAL APPLICATION WITH THE
INTERNATIONAL SEARCH REPORT (PUB. OF THE
INTERNATIONAL APPL. WITH THE INTERNATIONAL
SEARCH REPORT)

WO 9801116 P 19980212 WO DFPE REQUEST FOR PRELIMINARY
EXAMINATION FILED PRIOR TO EXPIRATION OF 19TH
MONTH FROM PRIORITY DATE

WO 9801116 P 19980506 WO 121 EP: PCT APP. ART. 158 (1)
(EP: PCT ANM. ART. 158 (1))

WO 9801116 P 19990604 WO NENP NON-ENTRY INTO THE NATIONAL
PHASE IN:
JP 1998505391

WO 9801116 P 20000109 WO NENP NON-ENTRY INTO THE NATIONAL
PHASE IN:
CA

WO 9801116 P 20000112 WO 122 EP: PCT APP. NOT ENT. EUROP.
PHASE (EP: PCT ANM. NICHT IN EUROP. PHASE
EING.)

WO 9801119 P 19960709 WO AA PRIORITY CLAIMED
US 21420 P 19960709

WO 9801119 P 19960828 WO AA PRIORITY (PATENT)
GB 9617898 A 19960828

WO 9801119 P 19961031 WO AA PRIORITY CLAIMED
US 29351 P 19961031

WO 9801119 P 19970703 WO AE APPLICATION DATA (APPL.
DATA)
WO 97US10867 A 19970703

WO 9801119 P 19980115 WO AK DESIGNATED STATES CITED IN A
PUBLISHED APPLICATION WITHOUT SEARCH REPORT
(DESIGNATED STATES CITED IN A PUBLISHED APPL.
WITHOUT SEARCH REPORT)
AL AM AU AZ BB BG BR BY CA CN CZ EE GE HU IL
IS JP KG KR KZ LK LR LT LV MD MG MK MN MX NO
NZ PL RO RU SG SI SK SL TJ TM TR TT UA US UZ
VN YU AM AZ BY KG KZ MD RU TJ TM

WO 9801119 P 19980115 WO AL DESIGNATED COUNTRIES FOR
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APPLICATION WITHOUT SEARCH REPORT

(DESIGNATED COUNTRIES FOR REGIONAL PATENTS
CITED IN A PUBLISHED APPL. WITHOUT SEARCH
REPORT)

GH KE LS MW SD SZ UG ZW AT BE CH DE DK ES FI
FR GB GR IE IT LU MC NL PT SE BF BJ CF CG CI
CM GA GN ML MR NE SN TD TG

WO 9801119	P	19980115	WO A2	PUBLICATION OF THE INTERNATIONAL APPLICATION WITHOUT THE INTERNATIONAL SEARCH REPORT (PUB. OF THE INTERNATIONAL APPL. WITHOUT THE INTERNATIONAL SEARCH REPORT)
WO 9801119	P	19980312	WO DFPE	REQUEST FOR PRELIMINARY EXAMINATION FILED PRIOR TO EXPIRATION OF 19TH MONTH FROM PRIORITY DATE
WO 9801119	P	19980506	WO 121	EP: PCT APP. ART. 158 (1) (EP: PCT ANM. ART. 158 (1))
WO 9801119	P	19990604	WO NENP	<u>NON-ENTRY</u> INTO THE NATIONAL PHASE IN: JP 1998505217
WO 9801119	P	19991110	WO 122	EP: PCT APP. NOT ENT. EUROP. PHASE (EP: PCT ANM. NICHT IN EUROP. PHASE EING.)
WO 9801119	P	20000109	WO NENP	<u>NON-ENTRY</u> INTO THE NATIONAL PHASE IN: <u>CA</u>